

Applicants: Aguilar Rubido et al.
Serial No.: 10/501,570
Filed: September 27, 2004
Response to Non-Final Office Action
Page 6 of 7

Remarks

This Amendment is in response to the office action mailed May 14, 2007. Claim 1 has been amended. Accordingly claims 1-3, and 13-20 are pending. In view of the arguments and amendments set forth herein, reconsideration is respectfully requested.

Rejection under 35 U.S.C. 103(a) over Schmitt, Alpar, and Isaka in view of EP0864649A2

On pages 2-5 of the Office Action, Claim 1-3 and 13-20 were rejected under 35 U.S.C. 103(a) for allegedly being obvious over Schmitt et al., Alpar et al., and Isaka et al. in view of EP 0864649A2. Applicants respectfully disagree.

The vaccine claimed in independent claim 1 is not disclosed by Schmitt and/or the other cited references. Independent claim 1 has been amended to specify that the *Bordatella pertussis* is whole-cell. Support for this amendment can be found, for example, on page 16, line 29 of the specification. The *Diphtheria-tetanus-acellular pertussis* vaccine taught by Schmitt is acellular, not whole cell. None of the other references cited by the examiner indicate the use of *Bordatella pertussis* either whole-cell or acellular. Accordingly, claims 1-3 and 13-20 as amended are not obvious over the cited references.

Examiner contends that Isaka et al. teaches the safe and effective intranasal administration of HBsAg with or without the adjuvant rCTB. The Examiner also asserts that Alpar et al. teaches intranasal administration of TT/DT with a “verity of adjuvants”. Both Alpar and Isaka teach the need for an adjuvant when administering vaccines intranasally in order to elicit a protective effect. Neither indicates intranasal administration of HBsAg as that adjuvant.

EP 0864649A2 teaches only that said HBsAg exhibits greater immunogenicity than HBsAg produced via alternative methods. Furthermore, the enhanced

Applicants: Aguilar Rubido et al.
Serial No.: 10/501,570
Filed: September 27, 2004
Response to Non-Final Office Action
Page 7 of 7

immunogenicity taught by EP 0864649A2 is only evaluated using parenteral administration of a singular vaccine – no combination of vaccines is evaluated. The enhanced immunogenicity seen in the HBsAg produced by *Pichia pastoris* is not known to extend beyond to HBsAg to create an adjuvant effect on other vaccines co-administered.

Accordingly, for the reasons given above, applicants respectfully request that the rejection of claims 1-3 and 13-20 under 35 U.S.C. 103(a) over Schmitt et al., Alpar et al., Isaka et al., and EP 0864649A2 be reconsidered and withdrawn.

In view of the above, allowance of the pending claims is earnestly requested. If the examiner has any questions regarding this amendment, she is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



Ellen N. Hollcroft
Registration No. 58,452
Attorney for Applicants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(516) 822-3550
ENH/jp